

### **AMENDMENTS TO THE DRAWINGS**

The attached replacement sheets of drawings include changes to FIGS. 3-5. These sheets, which include FIGS. 1-6, replace the original sheets including FIGS. 1-6. Previously dark sections of FIGS. 3, 4, and 5 have now been re-drafted to more clearly illustrate what is being shown.

Attachment: Replacement Sheets

### **REMARKS**

The Office Action mailed February 8, 2007 has been received and reviewed. Prior to the present amendment, claims 1-51 were pending in the subject application, of which claims 8, 9, 17, 25, 26, 34, 42, 43, and 51 were withdrawn from consideration and claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 were rejected. More specifically, claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Further, claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2002/0110823 to Hogan (hereinafter the "Hogan reference") in view of Usami et al., J. Human Genetics (1999) vol. 44/5, pp. 304-307 (hereinafter the "Usami reference"). Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

#### **Amendments to the Claims**

Claims 1, 5, 10-15, 18, 22, 27-32, 35, 39, and 44-48 have been amended herein. Care has been exercised to avoid the introduction of new matter. Support for the various amendments can be found in the Specification. *See, e.g., Specification*, at p. 11, ¶ [0032]; p. 12, ¶¶ [0034]-[0035].

#### **Rejections based on 35 U.S.C. § 112 ¶ 2**

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50, have been amended, either directly or by way of amendment to an independent claim

relied upon by a dependent claim, to overcome the indefiniteness rejection and are believed to be in condition for allowance.

**Rejections based on 35 U.S.C. § 103(a)**

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestions or motivations found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, *Application of Bergel*, 292 F. 2d 955, 956-957 (1961). Thus, in order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” See MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated

teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application].” *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 103 as being unpatentable over the Hogan reference in view of the Usami reference. As neither the Hogan reference nor the Usami reference, either alone or in combination, teach or suggest all of the claim limitations of independent claims 1, 18, and 35, Applicants respectfully traverse this rejection as hereinafter set forth.

As currently amended, independent claim 1 recites a method in a computer system for preventing atypical clinical events related to information identified by DNA testing a person which comprises, in part, receiving clinical agent information *input by a clinician*, the clinical agent information including an identifier of a *specific clinical agent*. As stated in the Specification, the present invention is directed to a computer information system that allows medical practitioners accessibility to clinical agent information and potential risks associated with polymorphism values. *Specification*, at p. 11, ¶ [0032]; p. 12, ¶¶ [0034]-[0035]. For example, the clinician may input clinical agent information by viewing “an expansive list of clinical agents, and select[ing] the desired agent by inputting [the name of] the desired agent . . . .” *Specification* at p. 11, ¶ [0033].

By way of contrast, the Hogan reference discloses a screening method for screening all anesthesia patients for potential complications. *See, e.g., Hogan reference* at p. 3, ¶¶ [0030]-[0031]; p. 10, ¶ [0113]. The Hogan reference fails to teach or suggest receiving

clinical agent information *input by a clinician*, where the clinical agent information includes identification of a *specific clinical agent*. *See generally Hogan reference*. More specifically, the Hogan reference teaches determining whether scheduled procedures involve genomic profiling. *See, e.g., Hogan reference* at p. 17, ¶ [0187]. If so, a sample is taken from the patient to create a genomic profile. *See id.* Then, in the Hogan reference, the genomic profile data is formatted to provide a clinician with information suitable for interpretation. *See, e.g., Hogan reference* at p. 17, ¶ [0190]. Once the clinician receives the formatted data, the clinician can select the proper drugs to be used with the patient. *See, e.g., Hogan reference* at p. 17, ¶ [0191]. As can be seen from a detailed analysis of the Hogan reference's teachings, the method in currently amended claim 1 is distinct from the screening method disclosed in the Hogan reference. Indeed, the Hogan reference fails to teach or suggest a clinician inputting a specific clinical agent, as required by currently amended independent claim 1. The Hogan reference instead teaches performing a screening and providing screening information to a clinician. *See generally Hogan reference*. Stated differently, the Hogan reference is directed to a screening procedure, whereas currently amended independent claim 1 is directed to an action in a computer system involving the receipt of clinical information input from a clinician. The Usami reference cited by the Examiner is unable to overcome the deficiencies of the Hogan reference. More particularly, the note-card with personal drug use information does not teach or suggest a clinician inputting a specific clinical agent, as required by currently amended independent claim 1. Thus, Applicants respectfully submit that the Hogan and Usami references, either alone or in combination, fail to teach or suggest each of the limitations of independent claim 1 under 35 U.S.C. § 103(a). Therefore, a *prima facie* case of obviousness has not been established for claim 1, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

With reference to independent claim 18, as currently amended, a computer system for preventing atypical clinical events related to information identified by DNA testing a person is recited which comprises, in part, a receiving component that receives clinical agent information *input by a clinician*, the clinical agent information including an identifier of a *specific clinical agent*. As previously stated, neither the Hogan reference nor the Usami reference, either alone or in combination, teach or suggest receiving a specific clinical agent input by a clinician. Thus, Applicants respectfully submit that the Hogan and Usami references, either alone or in combination, fail to teach or suggest each of the limitations of independent claim 18 under 35 U.S.C. § 103(a). Therefore, a *prima facie* case of obviousness has not been established for claim 18, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

With reference to independent claim 35, as currently amended, a computer-readable medium containing instructions for controlling a computer system for preventing atypical clinical events related to information identified by DNA testing a person is recited which comprises, in part, receiving clinical agent information *input by a clinician*, the clinical agent information including an identifier of a *specific clinical agent*. As previously stated, neither the Hogan reference nor the Usami reference, either alone or in combination, teach or suggest receiving a specific clinical agent input by a clinician. Thus, Applicants respectfully submit that the Hogan and Usami references, either alone or in combination, fail to teach or suggest each of the limitations of independent claim 35 under 35 U.S.C. § 103(a). Therefore, a *prima facie* case of obviousness has not been established for claim 35, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

Each of claims 2-7, 10-16, 19-24, 27-33, 36-41, and 44-50 depends, either directly or indirectly, from one of independent claims 1, 18, and 35. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness based upon the Hogan and Usami references, either alone or in combination, cannot be established for these claims for at least the same reasons as cited above. “‘If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.’ *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 2-7, 10-16, 19-24, 27-33, 36-41, and 44-50 is respectfully requested as well.

In addition to the reasons stated above, dependent claims 11, 28, and 45 are allowable over the Hogan reference in view of the Usami reference because of the included limitation that the list of one or more polymorphism values is *dynamically accumulated*. As stated in the Specification, the dynamic nature of the computer information system allows flexibility to update agent/gene associations and polymorphism/risk associations so that the system will have the most current information available. *Specification*, at p. 11, ¶ [0032]; p. 12, ¶¶ [0034]-[0035]. The invention of these claims places the best and most current evidence in the hands of clinicians at the point at which care decisions are made and received by the system. Neither the Hogan reference nor the Usami reference, either alone or in combination, teaches or suggests a dynamically accumulated list of polymorphism values. Instead, the Hogan reference discloses a static screening method using pre-determined markers for inclusion that is, by definition, incapable of the dynamic accumulation feature of dependent claims 11, 28, and 45. *See, e.g., Hogan reference* at p. 3, ¶¶ [0030]-[0031]; p. 10, ¶ [0113]. The physical note-card of the Usami reference does not cure this deficiency in the Hogan reference. *See generally Usami reference*. Thus, Applicants respectfully submit that, in addition to the reasons stated previously,

the Hogan and Usami references, either alone or in combination, fail to teach or suggest the dynamically accumulated feature of dependent claims 11, 28, and 45 under 35 U.S.C. § 103(a). Therefore, in addition to the above reasons, a *prima facie* case of obviousness has not been established for claims 11, 28, and 45, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejections of these claims.



**CONCLUSION**

For at least the reasons stated above, claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance for claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

No other fee is believed due in connection with this Amendment, but the Commissioner is hereby authorized to charge any additional amount required or to credit any overpayment to Deposit Account No. 19-2112.

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Respectfully submitted,



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